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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,914	09/24/2003	David W. Morris	20366-072001; PP023353.00	8849

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
05/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,914	MORRIS ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is noted that SEQ ID NOS: 4, 17, 32, 42, 50, 58, 74, 77, 87, 99, 112, 122, 145, 163, 169, 177, and 185 are human genomic sequences, and SEQ ID NOS: 5, 7, 9, 18, 20, 22, 24, 33, 35, 37, 43, 45, 51, 53, 59, 75, 78, 80, 82, 88, 90, 92, 94, 100, 102, 113, 115, 123, 146, 148, 150, 152, 154, 156, 158, 164, 170, 172, 178, 180, 186, 188, and 190 are human cDNA sequences (the instant specification, pages 103-104).

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group A. Claims 1-15, 45-48, drawn to a nucleic acid shown in tables 1-21, classified in class 536, subclass 23.1. Each nucleic acid constitutes a single, distinct invention.

Group B. Claims 16-21, 49, drawn to a polypeptide shown in tables 1-21, classified in class 530, subclass 350. Each polypeptide constitutes a single, distinct invention.

Group C. Claims 22-41, drawn to an antibody to a polypeptide shown in tables 1-21, classified in class 530, subclass 387.1. An antibody to each polypeptide constitutes a single, distinct inventiom.

Group D. Claims 42, 54-56, 61, drawn to a method for detecting cancer, using a polypeptide, shown in tables 1-21, classified in class 435, subclass 7.1. A method

for detecting each cancer, as recited on pages 12-15 of the specification, using each polypeptide constitutes a single, distinct invention.

Group E. Claims 43-44, 62-63, drawn to a method for treating cancer, using an antibody to a polypeptide shown in Tables 1-21, classified in class 424, subclass 130.1. A method for treating each cancer, as recited on pages 12-15 of the specification, using an antibody to each polypeptide constitutes a single, distinct invention.

Group F. Claims 50-53, drawn to a method for screening for a modulator of a nucleic acid shown in tables 1-21, classified in class 435, subclass 6. A method using each nucleic acid constitutes a single, distinct invention.

Group G. Claims 50-52, 57-60, drawn to a method for screening for a modulator of a polypeptide shown in tables 1-21, which modulates the polypeptide level, or modulates an activity of G- protein coupled receptor, tumor suppressor, nucleic acid binding, calcium binding, cell cycle regulation, mitosis, cell motility, electron transfer, and nucleotide binding, classified in class 435, subclass 7.1, classified in class 435, subclass 7.1. A method using each polypeptide, for screening each type of modulation, constitutes a single, distinct invention.

Group H. Claims 54, 61, drawn to a method for detection of cancer, by detecting one or more a nucleic acid shown in tables 1-21, classified in class 435, subclass 6. A method for detecting each cancer, using each nucleic acid or combination of nucleic acid constitutes a single, distinct invention.

Group I. Claims 62-63, 64, drawn to a method for treating cancer, using an inhibitor of a protein shown in tables 1-21, which inhibitor is a G-protein coupled receptor protein inhibitor, classified in class 514, subclass 2. A method for treating each cancer, as recited on pages 12-15 of the specification, using an inhibitor of each protein constitutes a single, distinct invention.

Group J. Claims 62-63, 65, drawn to a method for treating cancer, using an inhibitor of a protein shown in tables 1-21, which inhibitor is a nucleotide binding protein antagonist, classified in class 514, subclass 2. A method for treating each cancer, as recited on pages 12-15 of the specification, using an inhibitor of each protein constitutes a single, distinct invention.

Group K. Claims 62-63, 66, drawn to a method for treating cancer, using an inhibitor of a protein shown in tables 1-21, which inhibitor is a calcium binding protein antagonist, classified in class 514, subclass 2. A method for treating each cancer, as recited on pages 12-15 of the specification, using an inhibitor of each protein constitutes a single, distinct invention.

Group L. Claims 62-63, 67, drawn to a method for treating cancer, using an inhibitor of a protein shown in tables 1-21, which inhibitor is a nucleic acid binding protein antagonist, classified in class 514, subclass 2. A method for treating each cancer, as recited on pages 12-15 of the specification, using an inhibitor of each protein constitutes a single, distinct invention.

Group M. Claims 62-63, 68, drawn to a method for treating cancer, using an inhibitor of a protein shown in tables 1-21, which inhibitor is a cysteine-type

peptidase antagonist, classified in class 514, subclass 2. A method for treating each cancer, as recited on pages 12-15 of the specification, using an inhibitor of each protein constitutes a single, distinct invention.

Group N. Claims 62-63, 69, drawn to a method for treating cancer, using an inhibitor of a protein shown in tables 1-21, which inhibitor is a modulator of signaling or signal transduction, classified in class 514, subclass 2. A method for treating each cancer, as recited on pages 12-15 of the specification, using an inhibitor of each protein constitutes a single, distinct invention.

Group O. Claims 70-72, drawn to a method for treating cancer, using a nucleic acid inhibitor of a nucleic acid shown in tables 1-21. A method for treating each cancer, as recited on pages 12-15 of the specification, using an inhibitor of each nucleic acid constitutes a single, distinct invention.

The inventions are distinct, each from each other because of the following reasons:

A. Inventions A-C represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects.

The polynucleotides, the polypeptides and the antibodies are all structurally distinct molecules and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide is made by translation of mRNA, and the antibody is made by expression of a hybridoma. Further, the polynucleotide can be used for hybridization screening, the polypeptide can be used for methods of treatment, and the antibody can be used for antibody

binding detection. Furthermore, neither of the inventions is essential for the production of the other, and they have different modes of operation, different functions, and different effects. While a polypeptide can made by methods using the corresponding polynucleotide, it can also be recovered from a natural source using biochemical means. For instant, the polypeptide can be isolated, using affinity chromatography. Similarly, the antibody can be isolated from natural source, using biochemical means.

Further, it is noted that for unity of invention, the compounds have to (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential for that utility. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). In the instant application, although the different sequences could be used for detecting or treating cancer, however, the sequences for use in the claimed methods are distinct, because they do not share a substantial structure feature disclosed as being essential for detecting or treating prostate cancer.

Searching all the polynucleotides, the polypeptides and the antibodies would cause serious burden. In the instant case, the search of all the polynucleotides, the polypeptides and the antibodies are not coextensive. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to one polynucleotide which would not have described other polynucleotides, or the polypeptide, or the antibody thereof. Similarly, there may be journal articles devoted solely to the antibody, which would not have described the polypeptide, or the polynucleotide. Further, an amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies. Furthermore, antibodies,

which bind to an epitope of a polypeptide may be known even if a polypeptide is novel. As such, it would be burdensome to search the inventions of Groups A-C together.

B. The inventions of Groups D-O are materially distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The inventions of Groups D-O are materially distinct methods, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. The methods for detecting or treating different cancers are distinct, because different populations of cancer patients are used. Further, the method of diagnosis of a cancer, using a polynucleotide or a polypeptide, a method of treating using a polynucleotide or a polypeptide are all unrelated as they have different modes of operation, and differ in method steps and reagents used. For diagnosis of a cancer, using a polypeptide, quantitation of a labeled antibody that binds specifically to said polypeptide may be used. For diagnosis of a cancer, using a polynucleotide, hybridization assay may be used. For treatment of prostate cancer, a polynucleotide or polypeptide is administered to a patient having the disease, using any mode of administration. Thus, each group is unrelated as they comprise distinct steps and utilize different products, which demonstrates that each method has different mode of operation. Moreover, different products used in the different methods are distinct because they are different polynucleotides or polypeptides or antibodies with distinct structure and function, and would produce different effects. For these reasons the Inventions D-O are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The examination of all groups would require different searches in the U.S. patent shoes and the scientific literature and would require the consideration of different patentability issues. There may be journal articles devoted solely to detecting the presence of a cancer using a polypeptide, or a polynucleotide, which would not have described methods of detecting the presence of said cancer using another polypeptide, or another polynucleotide, or a method of treating prostate cancer, or vice versa. There may be journal articles devoted solely to detecting or treating a cancer, which would not have described methods of detecting or treating another cancer. Moreover, even if the method for detecting a cancer were known, the method of treating using the same products may be novel and unobvious, in view of the preamble and active steps. As such, it would be burdensome to search the inventions of Groups D-O together.

C. The invention of Group A and the methods of Groups F, H, O are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product (see MPEP 806.05(h)). In the instant case the polynucleotides product as claimed can be used in a materially different process such as in making the polypeptide, in addition to treating diseases.

Searching the inventions of Groups A and (F, H, O) together would impose serious search burden. The inventions of Groups A and (F, H, O) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotide and the method of detecting, or treating cancer, or a method for screening a

nucleic acid modulator are not coextensive. The search for Groups (F, H, O) would require a text search for the method of detecting, or treating cancer, or a method for screening a nucleic acid modulator, in addition to a search for the polynucleotide sequence of group A. Moreover, even if the polynucleotide product were known, the method of detecting, or treating cancer, or a method for screening a nucleic acid modulator, which uses the product may be novel and unobvious, in view of the preamble or active steps.

D. The invention of Groups B and (D, G, I-N) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product (see MPEP 806.05(h)). In the instant case the polypeptides product as claimed can be used in a materially different process such as in making an antibody, in addition to treating a disorder.

Searching the inventions of Groups B and (D, G, I-N) together would impose serious search burden. The inventions of Groups B and (D, G, I-N) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the polypeptide and the method of detecting or treating cancer, or a method for screening a polypeptide modulator detecting cancer, using the polypeptide are not coextensive. The search for Groups (D, G, I-N) would require a text search for the method of detecting or treating cancer, or a method for screening a polypeptide modulator, in addition to a search for the polypeptide. Moreover, even if the polypeptide product were known, the method of detecting or treating

cancer, or a method for screening a polypeptide modulator, which uses the product may be novel and unobvious, in view of the preamble or active steps.

E. The inventions of Groups C and (D, E) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody binding agent can be used to make affinity column, as opposed to treating a disorder.

Searching the inventions of Groups C and (D, E) together would impose serious search burden. The inventions of Groups C and (D, E) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibody and the method of detecting or treating cancer, using an antibody, are not coextensive. In addition, the search for Groups (D, E) would require a text search for the method of detecting or treating cancer, in addition to a search for the antibody. Moreover, even if the antibody product were known, the method of detecting or treating cancer, which uses the product may be novel and unobvious in view of the preamble or active steps.

Inventions of Group A and Groups (D, E, G, I-N) are unrelated because the product of group A is not used or otherwise involved in the processes of groups (D, E, G, I-N).

Inventions of Group (B, C) and Groups (F, H, O) are unrelated because the product of groups (B, C) is not used or otherwise involved in the processes of groups (F, H, O).

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH-TAM DAVIS
April 28, 2008

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643